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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,566	01/29/2004	Kiran K. Chada	69014-B/GJG	6434

7590 01/10/2007  
Gary J. Gershik  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, NY 11036

EXAMINER
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CHANDRA, GYAN

ART UNIT	PAPER NUMBER
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1646

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/768,566

Applicant(s)

CHADA ET AL.

Examiner

Gyan Chandra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of Application, Amendments, And/Or Claims**

Claims 10-16 are cancelled.

Claims 1-9 and 17 are pending and are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### ***Response to Arguments***

The rejection of claim 7 under 35 U.S.C. 112, first paragraph-enablement, is withdrawn in view of Applicant's arguments.

The rejection of claims 2-6 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicants arguments (see pg. 8 of Remarks filed on 10/23/2006).

### ***Claim Rejections – maintained***

### ***Claim Rejections - 35 USC § 112***

Claims 1-9 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants argue that the instant specification on pg.13-14 discloses "sFRP-5" as a polypeptide of SEQ ID NO: 1.

Applicants' argument that the specification teaches that the sFRP-5 is a polypeptide is persuasive. However, the term "sFRP-5" is not well known in the art.

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Therefore, a relevant search cannot be performed. However, an amendment to claims 1, 7 and 17 reciting a sequence identifier within a parenthesis after "sFRP-5" for example, sFRP-5 (SEQ ID NO: 1), could obviate this rejection.

Claims 1-9 and 17 remain rejected 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record on pg.3-6 of the previous office action.

Applicants argue (Response, page 5-6) that claim 1 recites a use of an "sFRP-5 peptide" or "a molecule effective to stimulate expression of the sFRP-5 peptide" to reduce an amount of adipose tissue in a subject. Applicants argue that the sFRP-5 is a specific polypeptide, and that the specification on page 14 discloses the polypeptide sequence. Therefore, the claim has the support for written description.

Applicants' arguments have been fully considered but they are not persuasive because claims 1-9 and 17 are drawn to a method of reducing an amount of adipose tissue in a subject comprising administering to the subject an amount of an "sFRP-5" or "**any molecule**" effective to stimulate expression of the sFRP-5 peptide. The specification discloses administering a molecule comprising the polypeptide sFRP-5 of SEQ ID NO: 1 to a subject. The written description in this case only sets forth an isolated polypeptide sFRP-5 (SEQ ID NO: 1) and therefore, written description is not in commensurate in scope with the claims which read on "any molecule" or a genus of "polypeptide" having 90%, 91%, 92%, 95% or 99% sequence identity to the polypeptide of SEQ ID NO: 1. The specification does not define the term "an sFRP-5 peptide" or

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"any molecule". Therefore, only the sFRP-5 peptide of SEQ ID NO:1 meets the written description guidelines (see Example 13 of <http://www.uspto.gov/web/menu/written.pdf>).

Claims 1-6, 8-9 and 17 remain rejected under 35 U.S.C. 112, first paragraph, while being enabling for administering the sFRP-5 of SEQ ID NO:1 to reduce adipose tissue, does not reasonably provide enablement for reducing the amount of adipose tissue in a subject by administering to the subject an effective amount of a molecule to stimulate expression of the sFRP-5 peptide that has (i) 90 % identity to the sequence of SEQ ID NO: 1, (ii) 91 % identity to the sequence of SEQ ID NO: 1, (iii) 92 % identity to the sequence of SEQ ID NO: 1, (iv) 95 % identity to the sequence of SEQ ID NO: 1, and (v) 99 % identity to the sequence of SEQ ID NO: 1.

Applicants argue (Response, page 6-8) that the polypeptide sFRP-5 of SEQ ID NO: 1, when administered to a wild-type animal, reduces adiposity. Applicants' arguments are persuasive for administering the polypeptide of SEQ ID NO: 1 in a subject for reducing adipose tissue. However, Applicants' arguments are not persuasive for reducing adipose tissue in a subject comprising administering any molecule or a polypeptide that has at least 1-10% variation to the polypeptide of SEQ ID NO: 1 (sFRP-5) for the reasons of record set forth in the office action of 4/19/2006.

***Claim Rejections - 35 USC § 102***

Claims 1-9 and 17 remain rejected under 35 U.S.C. 102(e) as being anticipated by Xu et al (US 2003/0143610) for the reasons of records on pages 11-12) of the office action mailed on 4/9/2006.

Applicants argue (Response, page 9) that the reference Xu et al do not administer sFRP-5 to a subject. Therefore, Xu et al did not inherently do anything at all because there was no actual administration of sFRP-5 to a subject and therefore, the effect of such administration was not present in Xu et al.

Applicants' arguments have been fully considered but they are not persuasive because Xu et al teach using SARP3 (identical to sFRP-5) for modulating SARP3 mediated metabolic diseases or disorders in a subject (see abstract). Xu et al., specifically teach administering to a subject having a metabolic disorder comprising the SARP-3 polypeptide of SEQ ID NO: 2 [0018]. Further Xu's protein is the exact same protein as applicants. And, since the product of the prior art is identical to that required by the claims, the method will inherently lead to the same therapeutic outcome in a subject. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993). Thus, since the product of the prior art has the same chemical structure as that described in the specification, it can be assumed that the product will inherently perform the claimed process. (See MPEP 2112.02).

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

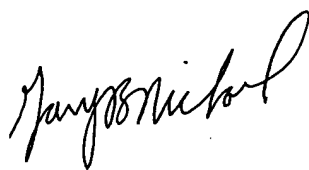
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra, Ph.D.  
Art Unit 1646  
14 December 2006  
Fax: 571-273-2922



GARY B. NICKOL, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600